MDSAP RA QMS IMPLEMENTATION PLAN

Project Title

Recommendations on the design and implementation of a Medical Device Single Audit Program (MDSAP) Quality Management System (QMS)

1. Purpose

To develop recommendations on the planning, designing, development and implementation of a quality management system that will be used by Medical Device Single Audit Program (MDSAP) Regulatory Authorities (RA)

2. Background

SME work item

The MDSAP Subject Matter Expert group agreed at their April, 2014 monthly meeting to form a task group to develop a paper that would provide recommendations on the design and implementation of a multi-site MDSAP QMS. The task group has been instructed to complete the paper by September 30, 2015.

The purpose of the multi-site MDSAP QMS is to control all MDSAP related activities that take place at, and across, the RA sites in Australia, Brazil, Canada, Japan and USA. The task group was specifically instructed to develop recommendations on:

- how the MDSAP QMS is to be used by each RA;
- who at each RA site will use or be affected by the MDSAP QMS; and
- when the MDSAP QMS would come into force.

The task group was also given the authority to provide recommendations on other related aspects of the MDSAP QMS. To this end, the task group has agreed to develop recommendations on:

- the scope (location and processes) of the MDSAP QMS;
- the QMS standard that would be adopted;
- the QMS processes and procedures, or aspects of the process or procedure, that would have to be established and implemented at each RA site; and
- the roles and responsibilities of the positions identified as using or being affected by the QMS.

Why a MDSAP QMS?

The purpose of a multi-site MDSAP QMS is to: i) assist MDSAP RAs in consistently conforming with MDSAP procedures and policies; and ii) demonstrate to internal and external parties that MDSAP is an effective international program for the recognition of third-party Auditing Organizations (AO) to have the ability to consistently audit medical device manufacturers for regulatory purposes.

Basis of MDSAP recognition

The MDSAP AO recognition process relies upon procedures and documents that have been developed by the MDSAP SME group and the MDSAP IMDRF working group. Documents used in the recognition process are:

- IMDRF/MDSAP WG/N5 (Regulatory Authority Assessment Method for the Recognition and Monitoring of Medical Device Auditing Organizations), IMDRF/MDSAP WG/N6 (Regulatory Authority Assessor Competence and Training); and IMDRF/MDSAP WG/N11 (MDSAP Assessment and Decision Process for the Recognition of an Auditing Organization)
- MDSAP Assessment Procedures (MDSAP AS P0005 and AS P0021)
- MDSAP QMS manual (MDSAP QMS P0001) and MDSAP procedures (MDSAP QMS P0002 to MDSAP QMS P0015).

Regulatory Authorities located in Australia, Brazil, Canada, Japan and USA have implemented national regulations related to medical devices sold or distributed in their countries. The intent of these regulations is to ensure that medical devices are manufactured or designed and manufactured according to requirements like ISO 13485:2003, Quality System Regulation 21 CFR part 820 and Brazilian Good Manufacturing Practices RDC ANVISA 16/2013 and Japan PMDA regulations. Recognised AOs will be considered competent to simultaneously audit these regulatory and ISO requirements.

Team members

TGA: Dragana Milic and Keith Smith
ANVISA: Fernanda Maia and Patricia Serpa
HC: John Helmkay
PMDA: Kenichi Ishibashi
FDA: Liliane Brown

3. Proposed Recommendations

3.1. Coming into force date of MDSAP QMS

Modern complex multi-site quality management systems rely on secure, scalable and enterprise-wide computer based software to manage workflows, documents and records of the system. An MDSAP RA team is currently working with external experts and software suppliers to purchase and implement a computer based solution that is informally called the "MDSAP Portal". It is envisaged that the Portal will not only function as a tool to manage and store documents related to the AO recognition process but it will also act as a secure electronic tool to manage and control MDSAP QMS documents and records.

Considering that the date of implementation of the Portal is at best 2 to 3 years away and full implementation of the MDSAP QMS will take time, the task group recommends that the MDSAP QMS implementation be carried out in 3 phases. The following describes the phases and the activities to be performed during each phase.

A. Phase 1 (January 1, 2015 – September 30, 2015):

1) MDSAP QMS task group to develop plan to design and implement the multi-site MDSAP QMS.

This document is the implementation Plan. It is based on specific task group recommendations. The MDSAP QMS framework, policy and objectives are described in the MDSAP QMS Quality Manual P0001.

2) MDSAP QMS task group defined the roles and responsibilities of positions required by the multi-site MDSAP QMS.

MDSAP QMS task group prepared a list with functions & QMS procedures. (Attachment 1) The document lists all functions mentioned in the QMS procedures and established in which hierarchy level they are located. (i.e. RAC, RA's, RA that has the RAC chair, SME's, etc.) With the definition of the functions including their locations it will be easier to know what is necessary to implement the QMS at each RA.

The critical positions, roles and responsibilities are considered to be:

<u>Top management (ISO 9001, clause 5.5.1) / MDSAP RAC</u>
The MDSAP Regulatory Authority Council (RAC) is the group that directs and controls the MDSAP organization at the highest level. The RAC will provide direction, oversight, and resources to support the MDSAP. The MDSAP RAC will

work with the top management at each Regulatory Authority to ensure that the MDSAP objectives are met and to ensure the availability of human and financial resources required to effectively implement and maintain MDSAP.

The RAC is composed of senior members of each RA.

An RAC RA member is appointed by the RA's management. Roles and responsibility of the RAC is defined in procedure MDSAP P0001.

Management representative (ISO 9001, clause 5.5.2) / MDSAP QMS Management representative

The Chair of the MDSAP RAC should appoint a member of the MDSAP Subject Matter Expert group as the MDSAP QMS "Management representative" for a fixed multi-year term of 3 years. (Keep same period that Chairmanship of the RAC rotates between each participating RA (MDSAP P0003).

The MDSAP QMS management representative will have appropriate knowledge and skill or work experience to:

- ensure that the multi-site MDSAP QMS processes are established, implemented and maintained;
- report to the RAC on the performance of the MDSAP QMS and any need to improve the system; and
- ensure the promotion of awareness of AO requirements across the RA sites.

To formally define who will assume each role and its responsibilities, MDSAP QMS Work Group prepared a list of functions and respective assigned representatives, which were nominated by each RA (Attachment 2).

Each RA appointed a person as the MDSAP QMS site representative. The QMS site representative will have the appropriate knowledge and skill or work experience to:

- ensure that the multi-site MDSAP QMS processes are established, implemented and maintained at their site;
- report to the MDSAP QMS management representative on the performance of the MDSAP QMS and any need to improve the system; and
- ensure the promotion of awareness of AO requirements at their site.

Human Resources (ISO 9001, clause 6.2) / RA Assessors & MDSAP Support Staff.

RA assessors are employees of the MDSAP regulatory authorities and are qualified to perform MDSAP AO assessments based on IMDRF/MDSAP WG/N6.

Qualified RA assessors are responsible for assessing MDSAP AO's against the criteria in ISO/IEC 17000:2004, IMDRF/MDSAP WG/N3 and IMDRF/MDSAP WG/N4 and for gathering evidence and evaluating it to determine the extent to which an AO has fulfilled recognition criteria.

Each RA should select assessors if the RA representative meets the RA assessor competency criteria in IMDRF/MDSAP WG/N6.

Each RA should select MDSAP support staff based on RA selection criteria.

3) MDSAP QMS task group to identify key elements of the MDSAP QMS that should be implemented before the MDSAP Portal is implemented, during the Phase II.

The MDSAP QMS Work Group identified the following key elements:

1) *Document & Record Control*
2) *Customer Complaint/Feedback*
3) *Quality Management Responsibilities and Management Review*
4) *Nonconformities - Corrective Action and Preventive Action (CA/PA)*
5) *Monitoring and measurement of processes*
6) *Internal "Quality" Assessments (Internal Audit)*
7) *Monitoring of Training requirements*

They shall be implemented in Phase II, as detailed below.

4) MDSAP QMS task group to define how the QMS will be used across all sites.

Each MDASP QMS site representative to review its own procedures and process to determine which MDSAP processes and/or procedures would have to be established and implemented at each RA site. The review process is to perform using form MDASP QMS F0008.2.

B. Phase 2 (October 1, 2015 - July 31, 2016):

Implement key elements of ISO 9001:2008 defined in Phase 1.

1) Customer Complaint/Feedback (high priority)

- MDSAP QMS management representative with assistance from QMS site representative to establish a full and complete complaint/feedback life-cycle system to address complaints quickly and effectively. The features of the process should provide an easy and systematic way of logging, tracking, ranking in terms of their seriousness, and alerting users when action is

needed. Additionally, allows analyzing data to determine problem areas, and determine what products and services (outcome) may need to be improved. RAs follow procedures MDSAP QMS P0011, P0009 and P0010.

2) *Quality Management Responsibilities and Management Review*
   - MDSAP top management, MDSAP QMS management representative, and MDSAP QMS site representative to carry our respective roles and to implement MDSAP QMS management review procedure MDSAP QMS P0005 and management review schedule.

   .

3) *Document & Record Control*
   - MDSAP RAs QMS management representative with assistance from QMS site representatives use multi-site document control procedure (MDSAP QMS P0002 & MDSAP QMS P0015) and records management system for documents, forms, and records.
   - MDSAP RAs QMS management representative and QMS site representatives to ensure that training related to new or revised documents is timely provided and training records are available.

4) *Corrective Action and Preventive Action (CA/PA)*
   - MDSAP QMS management representative with assistance from RA QMS site representatives implement multi-site corrective action and preventive action (CA/PA) system that includes mechanisms for collecting and tracking MDSAP quality issues at each RA site and for taking action where appropriate at one or more sites. RAs follow procedures MDSAP QMS P0009, MDSAP QMS P0010, and MDSAP QMS P0011.

5) *Monitoring and measurement of processes*
   - MDSAP QMS management representative with assistance from RA QMS site representatives collect Quality Metrics to track and assess operation of MDSAP QMS elements during Phase 2
   - MDSAP QMS management representative with assistance from RA QMS site representatives to collect Quality Metrics to track and assess impact of MDSAP on internal and external stakeholders
   - Quality metrics generated from customer feedback (MDSAP QMS P0011) and internal assessments (MDSAP QMS P0008).

6) *Internal "Quality" Assessments (Internal Audit)*
   - MDSAP QMS task group with assistance from RA QMS site representatives implement multi-site assessment procedure MDSAP QMS P0008 according to defined schedule and criteria.

7) Monitoring of Training requirements

- RA Training Representative with assistance from QMS site representatives and MDSAP RAs QMS management representatives to ensures that the MDSAP Training Program within their Regulatory Authority is implemented and that the RAC Secretariat or the MDSAP QMS management representative is provided the necessary training records from each MDSAP Team Member. RA follows procedure MDSAP QMS P0014.

C. Phase 3 (August 01, 2016 post Pilot):

Completed implementation and start assessing each RAs QMS site.

1) Scope (location and processes) of the MDSAP QMS

Locations

TGA	Manufacturing Quality Branch Medical Devices and Compliance Division Therapeutic Goods Administration Department of Health 50 Collie Street Fyshwick, Australian Capital Territory, Australia
ANVISA	Office of Medical Devices Inspection (Coordenação de Inspeção de Produtos Para a Saúde) – CPROD/GGINP/ANVISA SIA - Trecho 5, Área Especial 57 Zip Code: 71205-050 Brasília, Distrito Federal, Brazil
HC	Medical Devices Bureau, TPD, HPFB, Health Canada 2934 Baseline Road, 2nd Floor Qualicum, Tower B AL: 3403A Ottawa, Ontario, Canada, K1A 0K9
PMDA	Pharmaceuticals and Medical Devices Agency Office of Manufacturing/Quality and Compliance- Division of Registered Certification Body Assessment Shin-kasumigaseki Bldg. 3-3-2 Kasumigaseki, Chiyoda-ku Tokyo 100-0013, Japan
FDA	10903 New Hampshire Avenue-White Oak White Oak- Building 66 (HFZ-300) Silver Spring, Maryland 20993, USA

Processes:

Using criteria documents ISO 17021:2011, IMDRF/MDSAP WG/N3, IMDRF/MDSAP WG/N4, IMDRF/MDSAP WG/N5, IMDRF/MDSAP WG/N6, MDSAP Assessment Procedures (MDSAP AS P0005 to MDSAP AS P0021), MDSAP Quality manual (MDSAP QMS P0001) and MDSAP QMS procedures MDSAP QMS P0002 to MDSAP QMS P0015) perform initial and ongoing recognition of third-party Auditing Organizations.

The scope of the MDSAP QMS is limited to MDSAP related activities performed by MDSAP RAs.

2) QMS standard

MDSAP QMS to be based on ISO 9001:2008 – *Quality Management Systems – Requirements*.

The QMS framework builds upon or complements a RA's existing procedures and practices.

MDSAP RA sites that are currently operating according to an existing quality or business management system it is recommended that the MDSAP QMS not replace the existing QMS but operate in parallel with the existing quality or business management system.

3) Assessment and Program Evaluations

Assessments and Quality Management System Evaluations
Assessments and QMS evaluations are mechanisms to review an organizational component, system, process, enterprise, project, product, or program. Assessments and systems evaluations are performed within MDSAP.

Assessment should be conducted at planned intervals and using the MDSAP QMS checklist to determine whether the quality management system, including key business processes are consistent with ISO 9001:2008 – MDSAP QMS Framework, are being followed and are achieving stated objectives. It is important to start evaluating the quality management system starting during phase 2. It will allow for gathering data, and the subsequent analysis or organization of the data, in such a way that the resulting information can be used to determine whether the program or service is effectively carrying out planned activities, and the extent to which it is achieving its stated objectives and anticipated results.

Following an internal assessment, audit or program evaluation results should be analyzed, findings summarized and documented and, if needed, actions recommended to RAC.

Metrics will allow MDSAP participating Regulatory Authorities to evaluate the QMS Program. They will inform on the progress of establishing the QMS Program. Metrics will also be used to evaluate key business processes under the MDSAP QM Program. Results from metrics can lead to CAPAs and CPIs.

Metrics

MDSAP metrics will:

- assess the implementation of a process and any impact on subsequent processes of the MDSAP QMS Program;
- assess the outputs (products) of a process, and any impact on the quality of key business processes under the Quality Management Program; and
- assess customer perception and the fulfillment of customer requirements.

The following steps will assist in defining metrics:

- *Identify the process, output or outcome to be measured*. For each process, investigate the key goals and objectives and how they relate to the success of the MDSAP program.
- *Identify the customers/client*. Determine critical customer requirements or preferences.
- *Develop the method of measurement and the target metrics for each identified process, output, and outcome or customer requirement*. If measuring a step in a process (sub-process), make sure that method for measuring the sub-process does not adversely affect the measurement of the parent process.

    - For example, a method for the measurement of the AO's satisfaction with tools/forms for the preparation of audit report should not include a lengthy survey or other similar measure that would take significant time to complete. Such a survey would likely add time to the completion of the audit report and hence attract criticism from the AOs.

Monitoring

MDSAP QMS should monitor process data, including metrics, and establish appropriate methods for acting upon the findings and shall communicate the methods and tools used and the results to interested parties. Information monitored shall be periodically reviewed and corrective and preventive actions shall be taken when planned results and/or customer requirements are not met.

Data Collection and Analysis

MDSAP should identify and collect data on the performance of the quality management system and its processes, as well as for the products and services they provide.

Data should be systematically collected using appropriate information systems. Examples include:

- metrics;
- measures;
- non-conformances and corrective or preventive actions;
- satisfaction surveys; and
- results of assessments/audits.

4) Who at each RA site will use or be affected by the MDSAP QMS

The representatives in each position will be defined during phase 1 and 2:
See attachment 2: Listing RAs functions

5) Next steps

a. MDSAP QMS task group to comment and finalize the implementation plan document by August 30, 2015;
b. MDSAP SME submit final version of implementation plan to RAC for approval by September 15, 2015;
c. Goal to complete Phase 1 by September 30, 2015;
d. Goal to start phase 2 by October 2015 and have completed by July 31, 2016;
e. Phase 3; August 2016 start assessment of all MDSAP QMS RAs sites by using the assessment checklist;
f. Capture any NCs and improve QMS processes;
g. A MDSAP QMS document repository could be built in the FDA SFTP to meet the security concerns of all the RA's. All QMS activities performed and records generated can be captured independently until REPs has been implemented. A SFTP folder directory and structure will need to be defined to help organize the files that are shared amongst all RA's in the SFTP.

Version 001
Approval

Signature on file Date: 09/21/2015
Approved: Chair, MDSAP RAC

Annex 1 –

Evaluation of the current functions within MDSAP QMS

Attachment 1: RAs Role, Responsibilities and Functions

Diagram with functions & QMS procedures. The document lists all functions mentioned in the QMS procedures and established in which hierarchy level they are located. (i.e. RAC, RA´s, RA that has the RAC chair, SMEs, etc.)

Attachment 2: List of Representatives

Listing names at each RA site – who will be doing what